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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 8092008

Application Number: 09/815,336
Filing Date: March 23, 2003
Appellant(s): Kalloo, Anthony et al

Michell N. Lester
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 29, 2008.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) *Status of Claims*

The statement of the status of claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendments after final have been filed.

(5) *Summary of Claimed Subject Matter*

The summary of claimed subject matter contained in the brief is correct.

(6) *Grounds of Rejection to be Reviewed on Appeal*

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) *Claims Appendix*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) *Listing of Evidence Relied Upon*

The following is a listing of the prior art of evidence (e.g. patents, publications Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number
(Title)

Name

Date

| | | |
|-----------|---------------|-------------------|
| 5,297,536 | Wilk | March 29, 1994 |
| 5,458,583 | McNeely et al | October 17, 1995 |
| 6,030,365 | Laufer | February 29, 2000 |

(9) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 4, 5, 7-13, 15-19, 21, 22, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in combination with McNeely et al. Wilk teaches a method such as claimed, (see column 1, line 39 to column 2, line 64), except the specific mention of dilating the opening after it is made; the use of balloons; use of electrical energy in combination with the needle; and using a clip to seal the incision (please note that the absence of the use of a clip implies the absence of other steps predicated thereon, such as the disposing of a clip applicator). McNeely et al teach a method of dilating a stomach wall including inserting a needle to from an incision, advancing a guide wire through the incision; advancing a dilation balloon over the guide wire; dilating the incision with the dilation balloon, and advancing a tubular member into the dilated incision (see Figures 1, and 7-9; column 2, lines 1-24; and column 2, lines 35-54). It would have been obvious to the artisan of ordinary skill to employ the dilation steps of McNeely et al in the method of Wilk, since the method of Wilk requires the incision be made by a device in an auxiliary channel of the endoscope, which will necessarily be of considerably smaller gauge than the endoscope, thereby requiring dilation of the smaller opening made by the smaller device, and to first withdraw the balloon dilator before advancing the endoscope, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result; and to situate the balloon on the needle knife conduit, since this is not critical;

is well within the skill of one having ordinary skill in the art; provides no unexpected result; and since this would reduce the number of steps required to perform the operation, thereby saving time; and in any case to employ a clip to close the incision and the recited steps, since these are well known in the art and commercially available (see the paragraph spanning pages 15 and 16 of the instant disclosure), thus producing a method such as claimed.

Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in combination with McNeely et al as applied to claims 1, 2, 4, 5, 7-13, 15-19, 21, 22, and 36 above, and further in view of Laufer. Laufer teaches a method of accessing an internal organ including the use of a cauterizing incision instrument (see column 6, line 18-20) and the use of balloons to seal the conduit to either side of the incision in the organ wall (see Figure 4). It would have been obvious to the artisan of ordinary skill to employ a cauterizing incision device, as taught by Laufer in the combined method of Wilk and McNeely et al, since this is equivalent to the unheated needle of Wilk as shown by Laufer, and/or the balloon sealing means of Laufer in the combined method of Wilk and McNeely et al, since the use of balloons is not critical and provides no unexpected result, thus producing a method such as claimed.

(10) Response to Argument

A) Claims 1, 2, 4, 5, 7-13, 15-19, 21, 22, And 36 Are Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over Wilk in Combination With McNeely et al

Appellant argues that Wilk does not teach “the distal end of his flexible conduit through an incised target wall segment...” The examiner must respectfully disagree. Although not illustrated, Wilk clearly discloses that the endoscope can be enclosed in a sheath (see column 2, lines 15-22 and column 3, lines 52-61), which constitutes a flexible conduit, and which is

advanced through the opening in the wall segment (column 2, lines 40-45, and column 3, lines 62-66). With regard to the McNeely et al reference, appellant argues that this reference “does not simply teach a method of dilating the stomach wall” (see instant Brief, page 11, first full paragraph, the last sentence thereof), however, the mere fact that McNeely et al teaches additional methods or steps with regard to the dilation of the stomach wall does not negate the provision of the teaching employed by the examiner. McNeely et al specifically note that “sometimes the forces applied to the stomach wall to advance the dilators or the gastronomy tube are sufficiently high to cause the stomach wall to tear away from the T-fasteners” (see column 1, lines 47-50). Clearly, these forces (which would be transmitted to the esophagus or rectal opening in the Wilk method) would still be present regardless of the nature of the instrument (e.g. endoscope, dilator, gastronomy tube) which is being forced through the small incision which is present in the wall segment, and one of ordinary skill in the art would thus be motivated to employ measures such as the balloon dilation taught by McNeely et al to mitigate the attendant tissue injury that would otherwise result. Thus appellant’s assertion that “McNeely et al does not teach or in any way suggest that dilation of the incision(s) made by Wilk would be necessary or desirable” (see instant Brief, the paragraph bridging pages 11 and 12, the first sentence thereof) is unsupported by the references.

Next appellant asserts that because the procedure of McNeely et al is “long term” while that of Wilk is “short term” one of ordinary skill in the art would not pass the flexible conduit through the stomach wall as part of the sealing. Ignoring for the moment that the sheath of Wilk is also a flexible conduit, the passing of a conduit through a breach in a wall of the digestive tract is clearly disclosed as “exemplary” (see the first full sentence on page 7 of the originally filed

disclosure). Thus, even if, as asserted by appellant, the step were not present in the totality of teachings of the combination, the step has not been ignored by the examiner, it has simply been recognized that such a step would not represent a patentable advancement over the prior art "A person of ordinary skill is also a person of ordinary creativity, not an automaton." KSR International Co. v Teleflex Inc. 82 USPQ2d 1385, 1397 (Supreme Court, 2007). The passing of the conduit through the incision is provided, in order to provide sealing thereof as is well understood, this is set forth in the sentence bridging pages 6 and 7 of the originally filed disclosure. It is contested by appellant that one of ordinary skill in the art would seek to seal Wilk's perforation, noting that Wilk only teaches sealing engagement on one side of the wall. While this is true, the issue is not what the strict teachings of Wilk are, but what the disclosure of Wilk would teach one of ordinary skill in the art at the time of the invention, when combined with the teachings of McNeely et al. Looking at Wilk, one of ordinary skill in the art would readily realize that the use of suction to provide the seal in combination with insufflation would be somewhat counterproductive, as one is maintaining a seal using negative pressure (i.e. vacuum), while simultaneously pumping in gas at a positive pressure to expand the abdomen (i.e. insufflation {insufflate: "May involve injection of air or carbon dioxide into the peritoneum to achieve pneumoperitoneum during laparoscopy and laparoscopic surgery" Stedman's Medical Dictionary 26th Ed.}, see column 5, lines 1-18), this would also require the vacuum and insufflation to be applied continuously to maintain the inflated state of the peritonium. While this approach will work, one of ordinary skill in the art, who would be a thoracic surgeon, having not only 12 years of primary and secondary education, 4 years of college, 4 years of medical training, but also several years interning in thoracic surgery, will readily realize that the

continuous flow of gas throughout the procedure will dry out the tissues, in a similar fashion to the way the tongue and throat are dried out with continued breathing through the mouth. On the other hand, reliable and complete sealing of the opening is extremely important, as intimated in the sentence bridging pages 6 and 7 of the originally filed disclosure: "to provide a continuous path to and into the peritoneal cavity and to isolate the peritoneum from the gastric cavity." This is important in order to prevent chemical peritonitis ("Inflammation of the peritoneum due to escape of bile, contents of the gastrointestinal tract, or pancreatic juice into the peritoneal cavity; the contents of the fluid causes chemical injury, shock and peritoneal exudation prior to occurrence of any associated infection" Stedman's Medical Dictionary 26th Ed.), the dangers, possibilities, and causes of which one of ordinary skill in the art would have been well aware. Clearly these considerations are also operative in any procedure, long term or short term, that requires breaching of a wall of the digestive system, as such equivalent methods to provide this type of seal are employed in such situations. Thus the substitution of the sealing method of McNeely et al for that of Wilk would have been obvious since one of ordinary skill in the art would have also realized that alternate sealing methods, which would serve to prevent the leakage of gastric fluid into the peritoneum as the "combination of familiar elements according to known methods is likely obvious when it does no more than yield predictable results" KSR International Co. v Teleflex Inc. 82 USPQ2d 1385 (Supreme Court, 2007).

With regard to claims 13 and 15, appellant argues that the examiners determination of the obviousness of situating a dilation balloon on the needle knife conduit is a "summary conclusion". The examiner firstly notes the level of skill of one of ordinary skill in the art, as set forth above. Secondly, the examiner notes that the motivation for placement of the balloon on

the needle knife conduit was expressly stated: "reduce the number of steps required to perform the operation, thereby saving time" (see the Final Rejection mailed April 16, 2007, page 3, lines 2-3). Far from a summary conclusion, this motivation is clear and provides a desirable advantage that would be readily apparent to one of ordinary skill in the art. The shorter time for the procedure reduces the strain on the physician as well as the patient, who would also be required to be under anesthesia for a shorter time.

Next appellant asserts that the combination does not suggest the combination of claims 18 and 19 which requires the conduit of the needle-knife receives a guide wire and an inflatable balloon is provided on the conduit of the needle-knife device. The examiner respectfully disagrees. Again, noting the level of skill set forth above, the examiner further notes that the forming of an incision in the stomach wall with a needle (which, since it can be used to cut is considered a "needle-knife", see Wilk, column 2, lines 31-34), McNeely et al teach inserting a guide wire with a needle, which needle is then withdrawn, and dilators, including a balloon are slid over the guidewire to enlarge the opening (see McNeely et al column 5, line 65 to column 6, line 52 and Figures 3-8). Given that the procedure of Wilk is performed endoscopically, rather than on the surface of the body, as the procedure of McNeely et al, one of ordinary skill in the art would have understood that the needle insertion, guidewire insertion, and dilation would have to be conducted using endoscopic means, such as a conduit in which the needle need be delivered, using the same needle to introduce the guide wire, as to make the incision would, reduce the time and complexity of the operation, which is desirable, within the level of skill of one of ordinary skill in the art at the time of the invention, and obvious, as set forth above.

**B) Claims 6 And 14 Are Properly Rejected Under 35 U.S.C. 103(a) As Being
Unpatentable Over Wilk in Combination With McNeely Et Al, As Applied To Claims 1,
2, 4, 5, 7-13, 15-19, 21, 22, And 36, And Further In View Of Laufer**

Appellant argues, as above, that Wilk teaches sealing by suction and does not suggest that the tubular member is not passed through the stomach wall. These arguments are not convincing for the same reasons set forth above.

(11) Related Proceedings Appendix

NONE

(12) Conclusion

It is the examiner's firm opinion that the appealed claims are not patentable for the reasons argued above. Appellant has presented no convincing argument as to why the rejections set forth above are not obvious or proper. Therefore, it is respectfully submitted that the final rejection be affirmed.

Respectfully submitted,

/david shay/
Primary Examiner, Art Unit 3735
David Shay
September 13, 2008

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